**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

| | |
|---|---|
| MITSUBISHI CHEMICAL CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, ENCYSIVE PHARMACEUTICALS INC., GLAXO GROUP LIMITED AND SMITHKLINE BEECHAM PLC,<br><br>Plaintiffs,<br><br>v.<br><br>BARR LABORATORIES, INC. AND PLIVA-HRVATSKA D.O.O.,<br><br>Defendants. | Civil Action No. 1:07-CV-11614-JGK<br><br>**Electronically Filed** |

**ANSWER TO FIRST AMENDED COMPLAINT AND COUNTERCLAIMS**

Defendants Barr Laboratories, Inc. ("Barr") and Pliva-Hrvatska d.o.o. ("Pliva"), for their Answer and Counterclaims to the First Amended Complaint of Plaintiffs Mitsubishi Chemical Corporation ("Mitsubishi Chemical"), Mitsubishi Tanabe Pharma Corporation ("Mitsubishi Tanabe"), Encysive Pharmaceuticals Inc. ("Encysive"), Glaxo Group Limited ("Glaxo"), and SmithKline Beecham plc ("SmithKline"), aver as follows:

**Jurisdiction and Venue**

1. Defendants admit that Plaintiffs purport to state a claim for patent infringement under the patent laws of the United States, arising under 35 U.S.C. §§ 271(e)(2), 271(b), 271(c), and 281-283; purport to base subject matter jurisdiction on 28 U.S.C. §§ 1331 and 1338(a); purport to base venue on 28 U.S.C. §§ 1391(b)-(d) and 1400(b); and purport to base personal jurisdiction on N.Y. C.P.L.R. §§ 301 and 302(a).

**The Parties**

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 2 of the First Amended Complaint, and therefore deny them.

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 3 of the First Amended Complaint, and therefore deny them.

4. Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 4 of the First Amended Complaint, and therefore deny them.

5. Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 5 of the First Amended Complaint, and therefore deny them.

6. Defendants admit that Barr is a Delaware corporation with a place of business in Pomona, New York; admit that Barr's business includes manufacturing and marketing generic pharmaceuticals; admit that Barr is registered with the New York Department of State, Division of Corporations to do business in New York as a foreign corporation; and deny the remaining averments of paragraph 6 of the First Amended Complaint.

7. Defendants admit that Pliva has a place of business in Zagreb, Croatia; admit that Pliva's business includes manufacturing and marketing generic pharmaceuticals; admit that Barr is authorized to accept service of process for Pliva at 223 Quaker Road, P.O. Box 2900, Pomona, New York 10970; and deny the remaining averments of paragraph 7 of the First Amended Complaint.

8. Defendants admit that Barr, as agent for Pliva, filed Abbreviated New Drug Application ("ANDA") No. 79-238 with the United States Food and Drug Administration (the "FDA"); and deny the remaining averments of paragraph 8 of the First Amended Complaint.

9. Defendants admit that Barr does business in this judicial district; and deny the remaining averments of paragraph 9 of the First Amended Complaint.

10. Defendants admit that United States Patent No. 5,214,052 (the "'052 Patent") is entitled "Method for Dissolving Argininеamides and Pharmaceutical Compositions Containing Them"; admit that a copy of the patent is attached to the First Amended Complaint as Exhibit A; admit that the face of the patent states that it issued on May 25, 1993 to named inventors Kunihiko Ofuchi and Tatsuo Nomura; admit that the face of the patent states that it was assigned to the Mitsubishi Kasei Corporation of Tokyo, Japan; and deny the remaining averments of paragraph 10 of the First Amended Complaint.

11. Defendants admit that Mitsubishi Chemical is the recorded assignee of the '052 Patent; admit that the '052 Patent is scheduled to expire on June 30, 2014; admit that a patent term extension was granted pursuant to 35 U.S.C. § 156; and are without knowledge or information sufficient to form a belief as to the truth of the remaining averments of paragraph 11 of the First Amended Complaint, and therefore deny them.

12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 12 of the First Amended Complaint, and therefore deny them.

13. Defendants admit that FDA records indicate that Encysive is the holder of approved new drug application ("NDA") No. 020883 for the drug "argatroban" with the active

ingredient "argatroban" in the strength "100 mg/mL" in the dosage form/route of an "injectable/injection" (the "NDA Drug"); and are without knowledge or information sufficient to form a belief as to the truth of the remaining averments of paragraph 13 of the First Amended Complaint, and therefore deny them.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 14 of the First Amended Complaint, and therefore deny them.

15. Defendants deny the averments of paragraph 15 of the First Amended Complaint.

**The New Drug Application**

16. Defendants admit that FDA records indicate that NDA No. 020883 was approved on June 30, 2000; and are without knowledge or information sufficient to form a belief as to the truth of the remaining averments of paragraph 16 of the First Amended Complaint, and therefore deny them.

17. Defendants admit that the NDA Drug "is indicated as an anticoagulant for prophylaxis or treatment of thrombosis in patients with heparin-induced thrombocytopenia," and deny the remaining averments of paragraph 17 of the First Amended Complaint.

**COUNT I**
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(e)(2)(A) BY DEFENDANT)**

18. Defendants incorporate by reference their responses to paragraphs 1 through 17 of the First Amended Complaint as though fully set forth herein.

19. Defendants admit that Barr, as agent for Pliva, submitted ANDA No. 79-238 with the FDA under 21 U.S.C. § 355(j) seeking approval to market "Argatroban Injection,

100 mg/mL, 2.5 mL Vial" (the "ANDA Drug"), and deny the remaining averments of paragraph 19 of the First Amended Complaint.

20. Defendants admit that the ANDA Drug is considered bioequivalent to the NDA Drug, and deny the remaining averments of paragraph 20 of the First Amended Complaint.

21. Defendants admit that Barr, as agent for Pliva, submitted ANDA No. 79-238 seeking approval to engage in the commercial manufacture, use, and sale of the ANDA Drug before the expiration of the '052 Patent, and deny the remaining averments of paragraph 21 of the First Amended Complaint.

22. Defendants admit that by a letter dated November 16, 2007 (the "Notice Letter"), Barr informed Mitsubishi Chemical and Encysive that ANDA No. 79-238 was submitted with a certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV); admit that the Notice Letter was delivered to Mitsubishi Chemical and Encysive on or about November 19, 2007; and are without knowledge or information sufficient to form a belief as to the truth of the remaining averments of paragraph 22 of the First Amended Complaint, and therefore deny them.

23. Defendants admit that the Notice Letter is a "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act"; admit that the Notice Letter states, *inter alia*, that "the '052 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, importation, use or sale of" the ANDA Drug; and deny the remaining averments of paragraph 23 of the First Amended Complaint.

24. Defendants admit that the Notice Letter states that the FDA received ANDA No. 79-238 from Barr.

25. Defendants admit that a letter to Mitsubishi Chemical and Encysive dated January 15, 2008 (the "Clarification Letter") states that the name of the applicant in ANDA 79-238 is Pliva, and Barr is the authorized U.S. agent for Pliva related to the ANDA; and deny the remaining averments of paragraph 25 of the First Amended Complaint.

26. Defendants admit that by the Notice Letter dated November 16, 2007 and by letter dated January 15, 2007 (the "Revised Notice Letter"), Barr informed Mitsubishi Chemical and Encysive that ANDA No. 79-238 was submitted with a certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV); admit that the Revised Notice Letter was delivered to Mitsubishi Chemical on or about January 17, 2008; admit that the Revised Notice Letter was delivered to Encysive on or about January 16, 2008; and are without knowledge or information sufficient to form a belief as to the truth of the remaining averments of paragraph 26 of the First Amended Complaint, and therefore deny them.

27. Defendants admit that the Notice Letter and Revised Notice Letter each are a "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act"; admit that the Notice Letter and Revised Notice Letter each state, *inter alia*, that "the '052 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, importation, use or sale of" the ANDA Drug; and deny the remaining averments of paragraph 27 of the Complaint.

28. Defendants admit that the Notice Letter and Revised Notice Letter each state, *inter alia*, that "[e]ach of claims 1-4 of the '052 patent are invalid as obvious under 35 U.S.C. § 103(a) over Tamso Yoshikuni *et al.*, 'Alpha-(N-arylsulfonyl-L-Arginineamides, Process for Their Preparation and Pharmaceutical Composition Containing These Substances,' European Patent Application No. 79103092.7 ('Yoshikuni'), in further view of George M. Krause and John M. Cross, 'Solubility of Phenobarbital in Alcohol-Glycerin-Water Systems,'

*Journal of the American Pharmaceutical Association*, Vol. XL:137-139 (1951) ('Krause')"; and deny the remaining averments of paragraph 28 of the First Amended Complaint.

29. Defendants deny the averments of paragraph 29 of the First Amended Complaint.

30. Defendants admit that the Notice Letter and Revised Notice Letter each state, *inter alia*, that "the '052 patent is invalid, unenforceable, and/or will not be infringed by" the ANDA Drug, and deny the remaining averments of paragraph 30 of the First Amended Complaint.

31. Defendants admit that the Notice Letter and Revised Notice Letter each state, *inter alia*, that "the '052 patent is invalid, unenforceable, and/or will not be infringed by" the ANDA Drug, and deny the remaining averments of paragraph 31 of the First Amended Complaint.

32. Defendants admit that the Notice Letter and Revised Notice Letter each state, *inter alia*, that "any available objective evidence of nonobviousness is insufficient to rebut the *prima facie* case of obviousness," and deny the remaining averments of paragraph 32 of the First Amended Complaint.

33. Defendants deny the averments of paragraph 33 of the First Amended Complaint.

34. Defendants deny the averments of paragraph 34 of the First Amended Complaint.

35. Defendants deny the averments of paragraph 35 of the First Amended Complaint.

36. Defendants deny the averments of paragraph 36 of the First Amended Complaint.

**COUNT II**
**(INDUCEMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(b) BY DEFENDANT)**

37. Defendants incorporate by reference their responses to paragraphs 1 through 36 of the First Amended Complaint as though fully set forth herein.

38. Defendants deny the averments of paragraph 38 of the First Amended Complaint.

39. Defendants deny the averments of paragraph 39 of the First Amended Complaint.

40. Defendants deny the averments of paragraph 40 of the First Amended Complaint.

41. Defendants deny the averments of paragraph 41 of the First Amended Complaint.

42. Defendants deny the averments of paragraph 42 of the First Amended Complaint.

**COUNT III**
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(c) BY DEFENDANT)**

43. Defendants incorporate by reference their responses to paragraphs 1 through 42 of the First Amended Complaint as though fully set forth herein.

44. Defendants deny the averments of paragraph 44 of the First Amended Complaint.

45. Defendants deny the averments of paragraph 45 of the First Amended Complaint.

46. Defendants deny the averments of paragraph 46 of the First Amended Complaint.

47. Defendants deny the averments of paragraph 47 of the First Amended Complaint.

48. Defendants deny the averments of paragraph 48 of the First Amended Complaint.

49. Defendants deny the averments of paragraph 49 of the First Amended Complaint.

50. Defendants deny the averments of paragraph 50 of the First Amended Complaint.

51. Defendants deny the averments of paragraph 51 of the First Amended Complaint.

**AFFIRMATIVE DEFENSES**

**FIRST AFFIRMATIVE DEFENSE**

Defendants' manufacture, use, offer for sale, sale, and/or importation of the ANDA Drug pursuant to ANDA No. 79-238 has not directly infringed, does not directly infringe, and will not directly infringe any valid claim of the '052 Patent.

**SECOND AFFIRMATIVE DEFENSE**

Defendants' manufacture, use, offer for sale, sale, and/or importation of the ANDA Drug pursuant to ANDA No. 79-238 has not induced infringement, does not induce infringement, and will not induce infringement of any valid claim of the '052 Patent.

**THIRD AFFIRMATIVE DEFENSE**

Defendants' manufacture, use, offer for sale, sale, and/or importation of the ANDA Drug pursuant to ANDA No. 79-238 has not contributorily infringed, does not contributorily infringe, and will not contributorily infringe any valid claim of the '052 Patent.

**FOURTH AFFIRMATIVE DEFENSE**

The claims of the '052 Patent are invalid for failure to comply with the conditions for patentability as specified in Title 35 U.S.C. §§ 1 *et seq*.

**FIFTH AFFIRMATIVE DEFENSE**

The First Amended Complaint fails to state a claim against Defendants upon which relief can be granted.

**COUNTERCLAIM FOR DECLARATORY JUDGMENT**

Defendants and Counterclaim Plaintiffs Barr and Pliva, by their undersigned counsel, as and for their counterclaims against Plaintiffs and Counterclaim Defendants Mitsubishi Chemical, Mitsubishi Tanabe, Encysive, Glaxo, and SmithKline, aver as follows:

**Jurisdiction and Venue**

1. This counterclaim arises under the Declaratory Judgment Act and the Patent Laws of the United States, more particularly under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 1 *et seq.*, respectively. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1338 and 2201. Venue for these Counterclaims is proper under 28 U.S.C. §§ 1391(b)-(d) and 1400(b). Personal jurisdiction is proper under C.P.L.R. §§ 301 and 302(a).

2. An actual and justiciable controversy exists between Defendants and Plaintiffs as to the infringement and validity of the patents in suit, as evidenced, *inter alia*, by the Complaint, Answer, First Amended Complaint, and Answer To First Amended Complaint in this action.

**The Parties**

3. Barr is a Delaware corporation with a principal place of business in Pomona, New York, and is registered with the New York Department of State, Division of Corporations, to do business in New York as a foreign corporation.

4. Pliva has a place of business in Zagreb, Croatia.

5. Upon information and belief, based on the allegations of the First Amended Complaint, Mitsubishi Chemical is a Japanese corporation having its corporate headquarters and principal place of business in Tokyo, Japan.

6. Upon information and belief, based on the allegations of the First Amended Complaint, Mitsubishi Tanabe is a Japanese corporation having its corporate headquarters and principal place of business in Osaka, Japan.

7. Upon information and belief, based on the allegations of the First Amended Complaint, Encysive is a Delaware corporation having its corporate headquarters and principal place of business in Houston, Texas.

8. Upon information and belief, based on the allegations of the First Amended Complaint, Glaxo is a company organized and existing under the laws of England and Wales having its registered office in Greenford, England, and SmithKline is a company organized and existing under the laws of England and Wales having its registered office in Brentford, England.

**The Abbreviated New Drug Application**

9. Barr, as agent for Pliva, filed ANDA No. 79-238 with the FDA seeking approval for the ANDA Drug. ANDA 79-238 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that the ’052 Patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the ANDA Drug.

**COUNT I**

**Declaratory Judgment Of Invalidity Of The ’052 Patent**

10. The claims of the ’052 Patent are invalid for failure to comply with the conditions for patentability as specified in Title 35 U.S.C. §§ 1 *et seq*.

**PRAYER FOR RELIEF**

WHEREFORE, Barr and Pliva pray that the Court enter judgment against Plaintiffs:

A. Denying all relief sought in the First Amended Complaint, and dismissing the First Amended Complaint with prejudice;

B. Declaring that the claims of the ’052 Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the ANDA Drug pursuant to ANDA No. 79-238;

C. Enjoining Plaintiffs, their assigns, and all those in privity therewith from asserting the ’052 Patent against Barr, Pliva, or any of their customers or suppliers;

D. Awarding Barr and Pliva their attorneys’ fees pursuant to 35 U.S.C. § 285, and their costs and expenses; and

E. Awarding Barr and Pliva such other and further relief as may be just and proper.

4144237.6

Dated: New York, N.Y.
March 12, 2008

s/ Thomas J. Meloro
Thomas J. Meloro, Esq.
Diane C. Ragosa, Esq.
Heather M. Schneider, Esq.
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, NY 10019-6099
(212) 728-8000 Telephone
(212) 728-8111 Facsimile
TMeloro@willkie.com

*Attorneys for Defendant Barr Laboratories, Inc. And Pliva-Hrvatska d.o.o.*